

Claims

1. A device for insertion in a human or animal body and/or a body cavity, said device having inflatable/expandable means, **characterized** in that said inflatable/expandable means comprise at least one component capable of releasing
5 at least one low molecular drug capable of permeating into the adjacent tissue or body cavity.
2. A device according to claim 1, wherein said low molecular drug is a low molecular antimicrobial compound (LMAC).
3. A device according to claim 2, wherein the LMAC is released when said at
10 least one component is contacted with a second component.
4. A device according to claim 3, wherein said contact is accomplished through the introduction of a liquid selected from the group consisting of water, saline or any physiological buffer to said means.
5. The device according to claim 1, wherein said device is a catheter for insertion
15 into the urinary tract of said human or animal and said inflatable/expandable means comprise an inflatable cuff.
6. The device according to claim 5, wherein said cuff when inserted into the urinary tract is situated in the urinary bladder.
7. The device according to claim 1, wherein said device is an intratracheal tube.
- 20 8. The device according to claim 1, wherein said device is a gastric tube.
9. The device according to claim 2, wherein said LMAC is a reactive nitrogen intermediate, a reactive oxygen intermediate or a combination of these two.
10. The device according to claim 2, wherein the LMAC is selected from the group consisting of nitric oxide (NO), NO₂, N₂O₃, N₂O₄, HNO₃, HNO₂, NO⁺, NO⁻, O²⁻, O₃,
25 singlet oxygen, H₂O₂, OONO⁻, HOONO, NOCl, NOSC⁻, NO thiocyanate, an OH radical and HOCl.
11. The device according to claim 3, wherein said at least one component releasing a LMAC releases said LMAC upon acidification.
12. The device according to claim 11, wherein said at least one component is
30 nitrite.

13. The device according to claim 11, wherein said second component is ascorbic acid.
14. The device according to claim 11, wherein said at least one component is nitrite and said second component is ascorbic acid.
- 5 15. The device according to claim 3, wherein said at least one component releasing a LMAC releases the LMAC upon alkalisation.
16. The device according to claim 2, wherein said LMAC is in a gaseous state at body temperature.
17. The device according to any one of the claims above, having a concentration
10 of one or more metal ions in the contents of the inflatable/expandable means or in the material or the surface of said device, said concentration being sufficient to increase the antimicrobial effect.
18. A method for preventing and/or treating nosocomial infections originating from the insertion and/or use of a device inserted into a human or animal body and/or a
15 body cavity, said device having inflatable/expandable means, **characterized** in that at least one component capable of releasing at least one low molecular drug in said means is administered to said means, said low molecular drug permeating to the adjacent tissue and/or body cavity.
19. The method according to claim 18, wherein said low molecular drug is a low
20 molecular antimicrobial compound (LMAC):
20. The method according to claim 19, wherein the LMAC is released when said at least one component is contacted with a second component.
21. The method according to claim 20, wherein said contact is accomplished through the introduction of a liquid selected from the group consisting of water, saline
25 or any physiological buffer to said means.
22. The method according to claim 19 or 20, wherein said at least one component that releases a LMAC, an acidifying agent and/or said liquid is/are administered into said inflatable/expandable means, said means having an arrangement for administering said component that release at least one LMAC, said acidifying agent
30 in the cuff and/or said liquid.

23. The method according to claim 18, wherein said device is a catheter for insertion into the urinary tract of said human or animal body and said inflatable/expandable means comprise an inflatable cuff.

24. The method according to claim 18, wherein said device is an intratracheal tube for insertion into the respiratory tract of said human or animal body.

25. The method according to claim 18, wherein said device is a gastric tube for insertion into the gastrointestinal tract of said human or animal body.

26. The method according to claim 19, wherein said LMAC is a reactive nitrogen intermediate, a reactive oxygen intermediate or a combination of these two.

27. The method according to claim 19, wherein the LMAC is selected from the group consisting of nitric oxide (NO), NO_2^- , N_2O_3 , N_2O_4 , HNO_3 , HNO_2 , NO^+ , NO^- , O_2^- , O_3 , singlet oxygen, H_2O_2 , OONO^- , HOONO , NOCl , NOSCN , NO thiocyanate, an OH radical and HOCl.

28. The method according to claim 19, wherein said at least one component releases the LMAC upon acidification.

29. The method according to claim 28, wherein said at least one component is nitrite.

30. The method according to claim 28, wherein said second component is ascorbic acid.

31. The method according to claim 28, wherein said at least one component is nitrite and said second component is ascorbic acid.

32. The method according to claim 19, wherein said at least one component releases the LMAC upon alkalisation.

33. The method according to claim 19, wherein said LMAC is in a gaseous state at body temperature.

34. The method according to claim 19, wherein one or more metal ions are present in or introduced to the contents of the inflatable/expandable means, in a concentration sufficient to increase the antimicrobial effect.

35. A method for the prevention and treatment of nosocomial infections, characterized in that a device according to any one of the claims 1-17 is used.

36. A method for the prevention of nosocomial infections in patients having an urinary catheter inserted by preventing microbial growth in the collection device coupled to an urinary catheter, characterized in that at least one component releasing at least one low molecular antimicrobial compound (LMAC) is added to the
5 collection device.
37. The method according to claim 36, wherein said at least one component is nitrite that upon acidification releases a LMAC in the collection device.
38. The method according to claim 37, wherein the acidification is accomplished through the addition of an acidifying agent reducing the pH in the device to about pH
10 1 - 5.5, preferably to about pH 2 - 4.
39. The method according to claim 37, wherein the acidification is accomplished through the addition of ascorbic acid.
40. A kit to be used in the prevention and/or treatment of nosocomial infections originating from the insertion and/or use of a invasive medical device having an
15 inflatable cuff in a human or animal body and/or body cavity, said kit comprising said device and a syringe suitable for inflating said cuff, said syringe comprising the necessary components for the release of at least one low molecular antimicrobial compound (LMAC) after administration of said components into said inflatable cuff of said device.
- 20 41. The kit according to claim 40, wherein the device is a urinary catheter.
42. The kit according to claim 40, wherein the device is an intratracheal tube.
43. The kit according to claim 40, wherein the device is a gastric tube.
44. The kit according to claim 40, wherein said necessary components are present as powders that release said LMAC upon combination with a liquid such as
25 water, saline or any physiological buffer.
45. The kit according to claim 40, wherein said necessary components are present as separate solutions that are combined prior to administration or simultaneously with the inflation of said cuff.
46. A device for insertion in a human or animal body and/or body cavity, said
30 device having a compound integrated in its material or the surface thereof,

characterized in that said compound is one of ascorbic acid, a reactive nitrogen intermediate, a reactive oxygen intermediate or any combination of these.

47. A device according to claim 46, wherein said device is a catheter.

48. A device according to claim 46 or 47, wherein said compound comprises
5 nitrite.

49. A device according to claim 46 or 47, wherein said compound comprises nitrite in combination with ascorbic acid.

50. A device according to claim 46 or 47, wherein said compound comprises nitrite in combination with ascorbic acid and zinc.

10 51. A method for the prevention, treatment or alleviation of an abnormal state using a device according to claim 1.

52. A method according to claim 51, wherein said abnormal state is chosen among bacterial infections, viral infections, inflammatory states, and cancer.

15 53. A method according to claim 52, wherein the treatment is performed on the urogenital organs including one of the urethra, the prostate, the bladder, the vagina, cervix, uterus or oviducts.
